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09/824,905	04/02/2001	Sharat Singh	0225-0033.22	2421

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
1656	51

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/824,905	Applicant(s) 09/824,905
Examiner Joyce Tung	Art Unit 1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-10 is/are rejected.

7)  Claim(s) 4 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some\* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 86 20)  Other: \_\_\_\_\_

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## DETAILED ACTION

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-3, 5-7 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/824,851, claims 1-4 of copending Application No. 09/824,861 and claims 1-5 of copending Application No. 09/825,246. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-3, 5-7 and 10 are drawn to a kit comprising a set of electrophoretic tag probe which has the same feature as the set of the electrophoretic tag as claimed in claims 1-4 of copending Application No. 09/824851 and 09/824,861 except that the component T<sub>j</sub> of the probe of copending Application No. 09/824851 and 09/824,861 is a ligand capable of binding to or interacting with a target antiligand and the component L of the probe of copending Application No. 09/824851 and 09/824,861 is a linking

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group connected to  $T_j$ . So the component  $T_j$  of copending Application No. 09/824,851 and 09/824,861 encompasses the component  $T_j$  of copending Application No. 09/824,905 which is an oligonucleotide target binding moiety and the component L of copending Application No. 09/824,851 and 09/824,861 has the same function as the intersubunit linkage  $B_{i, i+1}$  of copending Application No. 09/824,905. The electrophoretic tag probe of instant claims 1-3, 5-7 and 10 also has the same feature as the electrophoretic tag probe of claims 1-7 of copending Application No. 09/825,246. Thus, an ordinary skill in the art at the time of the instant invention would have been motivated to construct the kit as claimed including the set of electrophoretic tag probe from the composition of the copending application since these electrophoretic tag probes have the same structural features.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-3, 5-7 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No.09/825,245. Although the conflicting claims are not identical, they are not patentably distinct from each other because the electrophoretic tag probe of instant claims 1-3, 5-7 and 10 has the same feature as the electrophoretic tag probe of the composition claims 1-9 of copending Application No.09/825,245 except that the set of the electrophoretic tag probe of copending Application No.09/825,245 is in the composition. Thus it would have been prima facie obvious to construct the kit as claimed.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Objections***

4. Claims 1-9 are objected to because of the following informalities: the letter "U<sub>1</sub>" in claims 1 and 9 might be typographic error. Appropriate correction is required.
5. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form because the limitations of claim 4 are drawn to the used of the set of electrophoretic tag probes there is no further limitation to the oligonucleotide sequence T<sub>j</sub>.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claims 1-10 are vague and indefinite because the subscript of the intersubunit linkages  $B_{i_{+1}}$  is unclear what is meant in claim 1. It is unclear how the language “a mobility modifier having a charge/mass ratio” is defined because it appears that every molecule has charges and mass. It is suggested to clarify uncertainty.
- b. Claims 1-10 are vague and indefinite because of the language “N is nucleotide joined to  $U_i$  in  $T_j$  through a nuclease-cleavable bond” in (a)(iii) and the language “where the e-tag reporter ( $D, M_j$ ) - N does not itself contain nuclease-cleavable bonds” in (a)(iv). It is unclear where is the nuclease-cleavable bonds. It is suggested to clarify uncertainty.
- c. Claims 1-10 are vague and indefinite because it is unclear what is the “j numbers”.
- d. Claims 9-10 are vague and indefinite because the language “the nuclease-resistant bond(s)” has no antecedent basis from where it is referred.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman et al. (5,470,705)

Grossman et al. disclose a probe comprising the feature of the e-tag probe as claimed in claim 1 and its dependent claims 2-3. The probe of Grossman et al. is captured (See column 20,

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lines 47-49). This is inherent that there is a capture agent bound to the probe (as recited in claim 1(b)). The probe includes a binding polymer, a polymer chain which imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57) (as recited in claim 1(a)). The probe is also cleavable with nuclease at the 5' end subunits from the probe and the probe releases a labeled probe composed of base, reporter and polymer chain (See column 19, lines 62-67 to column 20, lines 1-25) (as recited in claim 1(a)(iii)). The released probe is the same as the form (D, M<sub>j</sub>) - N structurally. Thus, it is inherent that in claim 1 (a)(iv) the e-tag reporter (D,M<sub>j</sub>) - N does not itself contain nuclease-cleavable bonds. The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). Other binding polymers are analogs of polynucleotides, such as deoxynucleotides with thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The feature of Grossman et al.'s probe anticipate the features of the claimed e-tag probe.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705), as applied to claims 1-3 above, and further in view of Babon et al. (5,851,770).

The teachings of Grossman et al. are set forth in section 9 above. Grossman et al. do not disclose that the probe contains a capture ligand as indicated in claims 5-8 and 10.

Babon et al. disclose a method for detecting one or more mismatches between a first and second nucleic acid in which the heteroduplex formed between the first and second nucleic acid sequence is biotinylated and captured by binding to streptavidin-magnetic beads (See column 7, lines 53-66). The capture ligand and capture agent includes antigen/antibody or DNA binding protein and its DNA binding site (See column 18, lines 13-24). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to modify the

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probe of Grossman et al. wherein the capture ligand and agent are attached to the oligonucleotide probe as taught by Babon et al.. The ordinary artisan would have been motivated to make this invention because directly capturing the probe to a solid support is easy to wash away the unbound probe which increases the accuracy of the method instead of capturing the probe through the immobilized target sequence as discloses by Grossman et al.

12 Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) as applied to claims 1-3 above, and further in view of Huie et al. (5,470,967).

The teachings of Grossman et al. are set forth in section 9 above. Grossman et al. do not disclose that the probe contains phosphodiester bond linkage and nuclease resistant bonds as claimed in claim 8.

Huie et al. disclose phosphodiester linkage in oligonucleotide analogs (See column 3, lines 59-62) and phosphorothioate diester shows increased resistance to nuclease (See column 3, lines 59-67). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to use the modified phosphodiester linkage as indicated by Huie et al. in the oligonucleotide probe of Grossman et al. because the use of the modified linkage of the oligonucleotide make them nuclease resistant (See column 3, lines 63-67).

13. The drawings are approved.

14. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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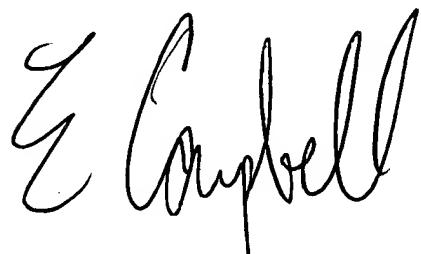
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

January 24, 2002



EGGERTON A. CAMPBELL  
PRIMARY EXAMINER